

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Gruening et al.

Examiner: Soo Yong Chung

Serial No.: 10/788,663

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For: ANTI-INFECTION HYDROGEL  
COMPOSITIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

**DECLARATION UNDER 37 C.F.R. §1.132**

Sir:

I, Rainer Gruening, declare as follows:

1. I have been Vice President of Research and Development at Hydromer, Inc. since June 4, 2001. Prior to this position, I held the position of Manager of Regulatory Affairs in AM Cosmetics. I have my Ph.D. in Chemistry from the University of Marburg in Germany. I am listed as an inventor on over 16 patents and have authored or co-authored 35 publications on the synthesis and formulations of antimicrobial polymeric coatings, cosmetics, adhesives and marine anti-fouling products.

2. I am co-inventor of the above-identified invention. The invention is a method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal by applying hydrogel compositions. The hydrogels comprise a poly(N-vinyl lactam), a polysaccharide and water. The hydrogels are lubricious aqueous gelatinous compositions.

3. The polyvinyl lactam and the polysaccharide of the hydrogels are present in a specific ratio. The range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5 : 1 to about 75 : 1.

4. The hydrogels of the instant invention have unexpected characteristics that could not have been predicted at the time of the instant invention. For example, the hydrogels exhibit certain sanitizing and disinfecting activity without the inclusion of antimicrobial/antibiotics.

5. Additionally, the hydrogels of the instant invention are unexpectedly fully reversible. In particular, the hydrogels break apart when forced through small holes, and then surprisingly recombine. Broken apart, the hydrogels form pieces with coarse/rough-appearing surfaces and uneven break lines. It is believed that the hydrogen bonds in these hydrogels are temporarily broken when such hydrogels are forced through small holes of applicators. The hydrogen bonds fuse together again after a few hours.

6. U.S. Patent Application No. 2002/0015697 ("*Beckman*") discloses a composition that includes a transition metal as the active ingredient. The *Beckman* composition reduces microbial populations by causing a "transition metal overload." The *Beckman* composition also includes a non-oxidant stress inducer, e.g., chitosan.

7. *Beckman* does not disclose a hydrogel. That is, *Beckman* does not disclose an aqueous lubricious gelatinous composition.

8. The only disclosure by *Beckman* of any kind of gel is at paragraph [0058]. And only "viscous gels" are mentioned. As defined in the art, "viscous" materials do not break apart, i.e., the bonds between the polymers do not break apart. Instead, viscous materials form smooth surfaces and tend to result in "long strings" of polymers when poured.

9. The fully reversible hydrogels of the instant invention can not be described as "viscous gels." The definition of viscous is "resistant to flow." Instead of resisting flow, the fully reversible hydrogels break apart and then reform again by fusing together.

10. *Beckman* mentions additional optional non-active ingredients that may be added to the composition. One of those ingredients is polyvinylpyrrolidone. However, *Beckman* does not specify any particular ratio of its non-oxidant stress inducer to the optional ingredient of polyvinylpyrrolidone.

11. In contrast, the specific ratios of the constituent ingredients of the compositions of the instant invention create their unique characteristic of being a fully reversible hydrogel and of having sanitizing/disinfecting properties.

12. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true. Further that these statements were made with the knowledge that willfully false statements, and the like, so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willfully false statements may jeopardize the validity of the application of any patent issued thereon.

  
Rainer Gruening